

1 question real well.

2 I would expect that there should be
3 performance requirements to support any claimed
4 cutoff, and it doesn't disturb me that much that they
5 can detect a drug below the cutoff. I would expect
6 that they should be able to.

7 But that I would certainly like to look at
8 that. Usually for a qualitative test of this sort,
9 you are actually in the fairly linear portion of the
10 curve when you are near the cutoff. So that
11 analytically they perform fairly well.

12 And the tests are qualitative because when
13 you go to much higher concentrations, then you lose
14 the linearity, but you don't care because they are
15 just positive. So I would be interested if the FDA
16 might even want to look at just how linear they are in
17 this region. That's all.

18 DR. KURT: Tom Kurt. I agree with the
19 previous speakers and would like to point out that the
20 kits that are being produced should be used exactly as
21 they are labeled, and that shortcuts or dividing them
22 up so that they are being used on two specimens, et

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1 cetera, is to save funds or a kit being reused, and
2 rejuvenated with some other re-agents, et cetera, is
3 not what is supposed to be done. It is supposed to be
4 used exactly as it is there, with the re-agents
5 contained within.

6 DR. WILKINS: Dr. Wilkins. With respect
7 to the first question, I think that I agree with Dr.
8 Kroll that I think, if anything, that I think the plus
9 50 percent and the minus 50 percent is somewhat
10 liberal.

11 I would be more in favor of tightening
12 that rather than widening that range to minus a
13 hundred percent, or plus a hundred percent. I mean,
14 I don't see the utility of the test or the benefit to
15 the consumer having quite that broad of a range.

16 I also might suggest that at least in the
17 guidance document that the term negligible performance
18 error be clearly defined for this issue, because I
19 think that leads to a lot of interpretation
20 variability, and that probably needed to be clearly
21 outlined.

22 DR. EVERETT: James Everett. Without the

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1 later aggression data and some evidence of what the
2 standard deviation would be, it is difficult to tell
3 whether the plus or minus 50 percent would include the
4 majority of samples or actually leave out a
5 significant number of samples.

6 But routinely a plus or minus 50 percent
7 should include the majority of samples clearly, as
8 opposed to screening out a lot of samples. I am not
9 sure if the manufacturers could actually meet such
10 criteria.

11 And again trying to define what the
12 negligible performance error would be, again that is
13 difficult to interpret without some data to help
14 evaluate whether the linear aggression curve actually
15 covers the majority of data that the test kits would
16 collect, because that is what you would like to do.

17 And that is that you would like to be able
18 to put the majority of samples in that range, and then
19 decide what the deviation should really be; whether it
20 is a plus or minus 25 percent, or plus or minus 50
21 percent.

22 But in essence, to start with, I think a

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1 plus or minus 50 is probably reasonable to start. But
2 I suggest that once a kit is developed and the data is
3 presented that that would have to be modified.

4 And then as it relates to question number
5 eight, should there be certain performance
6 requirements to support a claimed cutoff
7 concentration; again, you need the linear regression
8 data to determine that. But, of course, that is
9 standard for any statistical value that you will need
10 those numbers.

11 And if you are going to use a cutoff to
12 apply to whether or not a sample is negative or
13 positive, there should be some data to back that up.
14 So clearly I am in support of number eight.

15 That is, there should be some performance
16 requirements to support the claimed cutoff. You
17 should just pick one out of the air. That kind of
18 goes without saying.

19 DR. BUSH: Donna Bush. As to the first
20 question, the FDA suggests that OTC devices render
21 negligible performance error at plus or minus 50
22 percent of the cutoff. This is reasonable, and very

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1 reasonable.

2 When you think about what this first
3 initial test is part of, it is part of a system of
4 confirmation. So you want to get an accurate and
5 reliable -- a good feed into the confirmatory process
6 for those that need to be there, and you don't want to
7 miss some that should be going on to confirmation.

8 So you don't want to miss on the high
9 side, and the more on the low side that you get going
10 in, you are going to get laboratory confirmed
11 negatives coming back.

12 So people are going to have doubt and
13 wonder what is going on here with how tight that bell
14 curve is around the cutoff. So in a laboratory, plus
15 or minus 50 percent error would generate the antennae
16 to go up, and for one to start looking at what is
17 going on in your testing system.

18 So I think that is applicable also in this
19 type of technology. Visually read devices.
20 Absolutely. There should be performance requirements
21 to support the claimed cutoff.

22 And it is easy to do; whether it be the

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1 standard bell curve that goes back to the days of
2 radio amino assay, and you can talk about linear
3 ranges of the curves based on many different
4 approaches to finding a binding criteria. That's all.

5 MR. REYNOLDS: Stan Reynolds. On question
6 three, I agree with Dr. Wilkins and Dr. Everett that
7 you do need to define your negligible performance
8 error.

9 And also the comment that Dr. Henderson
10 made earlier, in that it would also be good to have
11 positive and negative predictive values, so that you
12 know in your population how frequently you may be
13 getting a false positive or false negative.

14 This is something that you know occurs in
15 one out of every 100 patients, and you get a false
16 negative, and you have someone that you have a strong
17 suspicion may be a drug abuser, and you may not accept
18 that value, and say maybe I need to do additional
19 testing.

20 If on the other hand it only occurs one in
21 every thousand, you may accept it. So I think that
22 you need both of these items for number three.

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1 On question number eight, obviously you
2 have to show how you came up with your cutoff. I
3 don't think that is a question. But the second
4 question because that if you set your cutoff at a
5 value that is different from the absolute sensitivity
6 in your system does that really matter.

7 In other words, if your system is actually
8 going to be more sensitive than what you are saying
9 your cutoff is, I don't see what the issue is there.
10 But you have to be able to document that whatever you
11 have established your cutoff is that it is reasonable,
12 and you have documentation to support that.

13 DR. LASKY: Fred Lasky. I agree with the
14 comments that have been stated, but I would like to
15 even get a little more specific. The issue with
16 negligible error, negligible performance error, is a
17 real bugaboo because when we are developing tests, we
18 think that we have negligible error, but all too often
19 it seems that when we come up with data, the FDA
20 disagrees.

21 And of course the hundreds of times that
22 we don't disagree, we all forget about. But the

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1 bottom line is that there is some definition about
2 that is really needed. Also, I think that I was
3 getting some mixed -- at least I was hearing what
4 appeared to be some mixed messages about this plus or
5 minus 50 percent.

6 That is related to the concentration, and
7 is compared to the cutoff, and is pretty typical of
8 the sort of things that are used and looked at for
9 qualitative tests. So you have a cutoff and you go
10 down 50 percent, and you go up 50 percent, and you see
11 how robust the test is at those points.

12 In the guidance document it says that
13 essentially all samples should give the correct
14 result, and again here essentially is a very
15 problematic word and needs some definition.

16 And I don't think that we are the group
17 right here to make that decision, but I think it is
18 the sort of thing that if a guidance is going to be
19 helpful, it has to provide some guidance, and I think
20 that is what is needed.

21 And another comment is that when you are
22 dealing with qualitative tests, often times you are

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1 not dealing with linear relationships. So those
2 statistics often times don't help.

3 But there was a guidance that was produced
4 by ECCLS, the European Committee for Clinical Lab
5 Standards, which is no longer in existence, but
6 fortunately the document still exists, that I think is
7 excellent to consider for determining the
8 characteristics of a qualitative test, in general, and
9 not just the drugs-of-abuse.

10 And obviously with drugs it is going to
11 get a lot hairier because of the impact of metabolites
12 on positive reports and negative reports if a test is
13 not quite sensitive enough.

14 With regard to number eight, I also agree
15 that the question needs some clarification, but as Mr.
16 Reynolds mentioned, often times the manufacturer will
17 have data certainly to support the claim.

18 The FDA requires that and if there is any
19 hope of getting a test cleared or approved, we have to
20 have data in order to support a claim. But also a
21 manufacturer often times may make a claim that is not
22 quite as good, whatever that means, as what has been

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1 submitted in order to make the test more robust for
2 the way it is intended.

3 So when I look at that question, I am not
4 sure as I think Mr. Reynolds mentioned, if that
5 limitation is good for the user, or if it is bad for
6 the user, in terms of providing some confusion or
7 clarity.

8 And I think that is really what has to be
9 looked at, and how the numbers are going to be used,
10 and whether or not it is really going to help the end
11 user interpret what the test kit is supposed to tell
12 him.

13 So I guess more guidance and definition is
14 really what I am looking for.

15 DR. KROLL: All right. Thank you. Then
16 we can go to the next group of questions.

17 DR. COOPER: These are related to study
18 design questions for drugs-of-abuse. Is the study
19 design as described in the guidance appropriate for
20 demonstrating performance of the device in the hands
21 of the lay user. Please consider sample size, use of
22 spiked samples, concentration range, and distribution

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1 of samples, and size of consumer study.

2 And the second question is the FDA is
3 suggesting that the sponsors conduct only the consumer
4 studies described in the OTC document when the device
5 has already obtained prescription clearance, and are
6 there any other studies warranted other than what was
7 described in the previous question.

8 DR. KROLL: Okay. Thank you. Why don't
9 we start with you, Dr. Lasky.

10 DR. LASKY: Okay. This is sort of a quick
11 think mode. For over-the-counter labeling, I think
12 there has been a lot of very helpful and substantial
13 guidance on how labeling should be divided for over-
14 the-counter use.

15 And I think that has been very helpful and
16 I don't mean to presume that the FDA is going to throw
17 all of that out, because I know that is not the case.
18 In my experience, which is not vast with OTC, but is
19 -- I do have some experience with it, when you hit
20 numbers with OTC devices, you really are getting into
21 a very sticky area.

22 I think the instructions for what to do

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1 with the result, and how in simple lay terms it can be
2 interpreted, including follow-up information, I think
3 is really the key here.

4 If too much is -- the critical issue of
5 too much is provided and most of it is useless, the
6 important things are not going to be seen, and I think
7 that is the key.

8 In terms of -- and so I don't advocate the
9 use of performance data for OTC as a general guide.
10 With regard to the study designs, I think the study
11 designs, in terms of in the hands of the user, I think
12 are general are fine from an overall perspective.

13 I do have some concerns about the very
14 strict, I would say, requirements or guidances, in
15 terms of the distribution of samples, because it may
16 not really suit the need of the particular device,
17 depending upon the full range and capability of the
18 device.

19 And also as we talked about a little bit
20 before, sometimes it is just -- it is virtually
21 impossible to get a large number of samples at all
22 different kinds and ends of the scale, and many times

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1 it is more important to get many samples so that you
2 see a variety of matrix, versus the full concentration
3 in the sort of sample distribution that has been
4 suggested.

5 That is not to say that challenging the
6 test is unimportant. It is. But there needs to be a
7 bit more flexibility on how that mix is actually
8 obtained.

9 MR. REYNOLDS: Insofar as the study design
10 in the sample size and things of that nature, I tend
11 to defer to the chemists and statisticians as to what
12 is appropriate for the actual design in the study. To
13 me it seems reasonable, but again I would defer that.

14 DR. BUSH: Donna Bush. The study design
15 question, I concur with what was presented by Dr.
16 Cooper earlier, in terms of the structure of that
17 study design.

18 And I concur with question number six, and
19 that's when the device has already obtained
20 prescription clearance, and I concur with that.

21 DR. EVERETT: James Everett. I tend to
22 agree with number five, in the sense that this kind of

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1 guidance should certainly be provided from previous
2 devices that we looked at.

3 There have been instances where the
4 manufacturer only reviewed less than five consumer
5 individuals in the study and that was disastrous. So
6 I think up front providing a potential manufacturer
7 with some idea of how many consumers must be involved
8 in the study, the sample size, as well as this
9 information we use to determine whether or not the
10 instrument actually works, is a very good idea,
11 because frequently the biostatisticians again come to
12 the forefront, and then they reorganize the data.

13 And it says though the manufacturer had no
14 idea how many individuals to include, what the sample
15 size should be, and again it is like they took the
16 data and then matched it to some statistical
17 calculation, and that is backwards. It shouldn't
18 really be done that way.

19 So I think up front that providing that
20 information is a very good idea; and then the other
21 one, I think that is pretty clear that it is just
22 necessary.

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1 DR. WILKINS: In answer to the first
2 question, I think that the model proposed for the
3 consumer studies is a very fair and reasonable place
4 to start for this type of testing. The only
5 additional comment that I have is that in terms of the
6 distribution of the samples -- well, that's probably
7 not quite what I mean, but the populations, or sort of
8 subgroups in which this is tested, that that needs to
9 be representative of the groups in which the test kit
10 will be used.

11 And I am not sure with this question when
12 you say the distribution of the samples, if you mean
13 the distribution of the number of samples in each of
14 the individual categories, plus or minus 50 percent,
15 or if you meant distribution of the samples, in terms
16 of the types of subgroups that might be looked at.

17 For example, different education levels,
18 or reading abilities, or whatever that might be. I
19 wasn't sure what the intent of that was for that
20 question. But I am assuming there that that means
21 that many different groups in which the kit might be
22 used would be included in the study or represented.

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1 And with number six, I agree. I don't
2 have anything to add to that, except that I think it
3 is reasonable to conduct only the consumer studies
4 when it already has prescription clearance.

5 DR. KURT: I agree with what has been
6 said, and I agree with the guidelines as presented by
7 Dr. Cooper earlier today, from the standpoint of
8 performance.

9 I am concerned that the spiked samples and
10 the definition be carefully defined to be sure how
11 those are really spiked. And in question six
12 concerning the consumer use, I think it would be
13 helpful to the manufacturer to trial it through a
14 small sampling of consumers before it actually gets
15 out there to be better prepared for problems that
16 might potentially occur, although you might not have
17 the full 200 consumer sampling size at that point.

18 DR. KROLL: Looking at question five, that
19 appears to be adequate. I think there needs to be
20 some care taken with spiked samples. Depending on
21 what the drug is, metabolites might be very important.

22 And in those cases probably it would be

1 better off using real samples, and if they can dilute
2 them with other samples that are of the same
3 approximate matrix, and then to get the appropriate
4 concentrations of drug that way. And that could be
5 determined by looking or using your reference method.

6 You might also want to consider adding in
7 the spiked samples as well. One thing we really have
8 not looked at is that in some cases you have to make
9 certain the spiked samples aren't the actual drug that
10 you are trying to measure, and that there is no
11 problem with being right or left oriented. That's
12 all.

13 DR. MANNO: On question number five, I
14 think everything is okay as it is presented. Dr.
15 Wilkins brought up a point on concentration and range,
16 and distribution of samples.

17 I originally thought of that as perhaps
18 knowing what the concentration of the sample being
19 tested is against whether you get a positive or a
20 negative result on it, and doing your statistics on it
21 that way. I appreciate the comments of the sponsors
22 about the difficulty in getting a large sized sample

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1 to test at a given concentration.

2 So I think that you could go about that
3 several different ways, but I think that generally
4 question five is okay. Question six, I agree with
5 that question, and I don't have any problems with
6 going ahead and just doing the consumer study on an
7 already approved product.

8 DR. LEWIS: Sherwood Lewis. All of the
9 good points have already been made by the previous
10 persons addressing these two questions and so I will
11 pass.

12 DR. HENDERSON: Cassandra Henderson. I
13 agree and have nothing to add other than just to point
14 out that certainly the post-marketing surveys should
15 be budgeted into all of the financial plans for the
16 sponsors.

17 DR. ROSENBLOOM: Rosenbloom. I agree with
18 the design as presented relative to question five, and
19 that consumer studies are all that would be needed if
20 the device has already been approved for prescription
21 use.

22 DR. KROLL: All right. Dr. Gutman, are

1 there any other points that you want to clarify on
2 these?

3 (No audible response.)

4 DR. KROLL: All right. Let's go to the
5 next set of questions.

6 DR. COOPER: Okay. I believe that this is
7 the last one. Oh, there is one more. The FDA does
8 not encourage inclusion of performance data in OTC
9 labeling. Do you feel such information should be
10 included?

11 If so, what types of studies should be
12 done to characterize performance well enough so that
13 it would be meaningful to the consumer? How should
14 performance be related to consumers in the labeling?

15 DR. KROLL: All right. Why don't we start
16 with Dr. Rosenbloom.

17 DR. ROSENBLOOM: Why don't we. I can
18 think of several reasons, but that is not the
19 question. I guess we are talking about OTC labeling
20 for all the various environments that we have been
21 discussing -- school, home, sports, and so on.

22 I think under the circumstances, given the

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1 variety of environments, that performance data should
2 be included. In some settings, you are going to be
3 dealing with rather sophisticated users, and actually
4 in all settings you may be dealing with sophisticated
5 users who want that information and others who won't.

6 The alternative is to give them a website
7 to find it on, which the sophisticated users will use.
8 They will probably find more information than you have
9 got in the labeling anyhow if they are really
10 interested.

11 But I don't see any downside to including
12 that information. What types of studies should be
13 done to characterize performance well enough so that
14 it would be meaningful to the consumer? I think the
15 kinds of statements that relate not so much to
16 sensitivity and specificity, and those kinds of
17 things, which a small range of consumers would be able
18 to understand.

19 But things like at such and such a level,
20 there is an X possibility, percent possibility, that
21 the test is truly negative and that you need to get
22 confirmation, and those kinds of statements relative

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1 to the linear performance.

2 And again you can't say what that will be
3 without having the data in front of you, but I think
4 people need to know what a specific result means in
5 very specific terms, and I think that could encourage
6 compliance with confirmatory testing.

7 DR. HENDERSON: I think there is no
8 question that study information should be included and
9 provided to consumers, and I certainly think that the
10 vast majority of consumers are capable of
11 understanding that, and I base that on trying to
12 discuss alpha fetal protein screening with women;
13 inner-city women in New York City, and middle class,
14 and very educated women, and they all have difficulty
15 understanding it.

16 But when given examples of false positives
17 and false negatives, and what they may mean, they
18 understand it, and they can make sense out of it, and
19 make an informed decision.

20 DR. LEWIS: Sherwood Lewis. I certainly
21 think that that information should be included in the
22 labeling, and I am just curious to know why FDA does

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1 not encourage the inclusion of this sort of
2 information, just for my own understanding.

3 DR. GUTMAN: Yes. There are at least two
4 reasons and we have obviously had internal discussions
5 and are interested in seeking outside input on this
6 issue. There are at least two reasons.

7 One is that it is very hard sometimes to
8 couch performance in a term that actually makes sense
9 to patients. It is easier said than done.

10 And the second is that our data threshold
11 for these submissions is clearly based on analytical
12 studies. I wish we did know the predictive value of
13 a negative or a positive in the actual intended use
14 setting, but we actually don't know that.

15 And so there has been in the internal
16 discussion about the pros and cons of putting the
17 performance in concerns that if the performance was
18 not carefully couched, that it could in fact
19 misrepresent the device.

20 I actually think that Dr. Rosenbloom's
21 suggestion of indicating at certain cutoffs what
22 positive and negative rates might be seen, and if you

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1 were to try something like that, you might create
2 understandable labeling.

3 But actually I think it would be
4 challenging, and I would be curious as to what the
5 rest of the group says.

6 DR. MANNO: Manno. I have nothing to add
7 to what has already been said.

8 DR. KROLL: Martin Kroll. Actually, I
9 agree especially with the comments of Dr. Rosenbloom
10 and the way that he stated them.

11 DR. KURT: Tom Kurt. I agree with merging
12 some of the good ideas of Dr. Rosenbloom and Dr.
13 Henderson, and to saying that in a simple sentence the
14 false positive rate, or the false negative rate is,
15 and for further information see our website at.

16 So you could have some performance data in
17 a simple nature there, but the more elaborate
18 information could be available and found at a website
19 for the more sophisticated person who probably would
20 have a computer to look it up.

21 DR. WILKINS: I would just state that I
22 agree with Dr. Rosenbloom's comments earlier and don't

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1 have anything additional to add.

2 DR. EVERETT: James Everett. Certainly
3 some information about performance should be included.
4 Obviously you would not put the raw data in there, but
5 once a responsible manufacturer develops a kit, they
6 should stratify the data so that if there are
7 obviously certain circumstances where the kit does not
8 perform well, then that information should be there,
9 and almost anybody can understand that.

10 For instance, if you are going to do the
11 test on the North Pole, it is freezing and it is
12 outside, and you do the test and it doesn't work.
13 Most people can understand that, and once the data is
14 evaluated, those kinds of things will usually surface
15 without a lot of effort.

16 And at the same time, they do affect
17 performance, and in a sense some of that kind of
18 performance information should be included. I don't
19 think we should just assume that they wouldn't
20 understand anything, but perhaps they don't have to
21 understand everything.

22 DR. BUSH: I concur with Dr. Rosenbloom

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1 and Dr. Henderson on their approach. Thanks.

2 MR. REYNOLDS: Stan Reynolds, and I also
3 agree with Dr. Rosenbloom and Dr. Henderson, and the
4 idea of a website or 800 number, where people could
5 call and get additional information and clarification,
6 and where if they did have a question that they could
7 just get a simple clarification from someone over the
8 telephone.

9 DR. LASKY: Fred Lasky. Under the
10 stressful situation of the last round, I can answer
11 this question partially. I would like to comment on
12 what Dr. Gutman said. We also have found that it is
13 like threading the eye of a needle to put in just the
14 right amount of information from a labeling
15 standpoint.

16 In general, I believe we need to be very
17 clear on how a kit should be used, the procedures and
18 under what conditions, as Dr. Everett mentioned. What
19 the results actually mean in terms that are
20 understandable to the lay user, so that we don't
21 confuse the user with a lot of information that he or
22 she might have to go to a professional to help

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1 clarify.

2 And thirdly I agree that if additional
3 information is requested that it should be available,
4 and I think of the kind of information that we
5 currently put in inserts, and instructions for us, as
6 we do with 510K products; and that being available if
7 requested I think is very, very appropriate, because
8 these sort of tests, over-the-counter tests, are used
9 often times -- and if you will excuse the expression
10 -- very sophisticated users, because they are easy to
11 use and often times very cost effective because of
12 things like time and through-put and all the other
13 things that we are all aware of.

14 DR. KROLL: Thank you. We have one more
15 question and that is question number seven.

16 DR. COOPER: Should only those devices
17 with SAMHSA cutoffs be eligible to be cleared for OTC
18 use and that is the last question.

19 DR. LASKY: Can I get a clarification from
20 Dr. Bush on what are SAMHSA's objectives? I am
21 familiar with some of the requirements, but I don't
22 frankly know why they are there, and I think that

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1 would be helpful in our discussion.

2 DR. BUSH: SAMHSA's objectives for
3 including the drugs that are on our testing panel?

4 DR. LASKY: Yes, and the mission also.

5 DR. BUSH: The mission, simply stated, in
6 the form of then President Reagan's executive order in
7 September of 1986, when he said there will be a drug
8 free Federal workplace. We are the largest employer
9 in the world, and we can make this happen and offer
10 employees a helping hand.

11 With that broad brush statement said, then
12 everybody had to interpret what does a drug free
13 Federal workplace mean. So the focus was placed on
14 illegal drugs of abuse, hence the classes of drugs
15 that were established then that remain today, and that
16 is marijuana, cocaine, PCP, opiates, and a focus on
17 heroin, and Tylenol with codeine compounds, and
18 refocused our efforts on heroin, the illegal drug-of-
19 abuse.

20 And amphetamines, and now we are looking
21 to broaden our horizon to include MDMA, MDA, MDEA, in
22 that broad brush, illegal drugs of abuse. And so when

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1 asked, well, why not include benzodiazapines, and
2 barbiturates, and we have been asked this multiple
3 times.

4 We interpret our mission as not to look at
5 diversion or misuse of prescription drugs, and so we
6 focus only on illegal drugs of abuse. So the classes
7 are marijuana, cocaine, PCP, opiates, morphine,
8 codeine, and then amphetamines.

9 DR. KROLL: Dr. Lasky, do you have any
10 comments on question seven?

11 DR. LASKY: Yes. Actually, thanks, Dr.
12 Bush. That was really very helpful. Based on that
13 and comparing that to the mission of the FDA, I don't
14 think that these guidances should be restricted to
15 those drugs because of the fact that there might be
16 other uses and reasons that over-the-counter testing
17 would be helpful for other classifications of drugs.

18 MR. REYNOLDS: Stan Reynolds, and I pretty
19 much agree with Dr. Lasky sitting here. There could
20 be other drugs, such as LSD, and things like that,
21 that a parent might want to be able to test their
22 child for, and someone may have a very good kit for

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1 that. So we should have the ability to look at some
2 of these other things.

3 DR. BUSH: Donna Bush. We would love to
4 find that marvelous LSD kit. Bring it on, please.
5 The short answer is please expand the panel. There is
6 multiple need out there for plenty more than just the
7 SAMHSA-5. Thank you.

8 DR. EVERETT: I agree.

9 DR. WILKINS: I agree.

10 DR. KURT: I agree that the panel should
11 be expanded, but I think those that are not the SAMHSA
12 drugs, the cutoffs as they are stated for kits, should
13 be stated how they were arrived at by, say, an
14 academic panel, et cetera, et cetera.

15 DR. KROLL: Martin Kroll. I agree. Also,
16 I think that it should be very clear if you are
17 looking at a drug that is not an examined a lot with
18 other methods that there are good reference methods
19 for it.

20 DR. MANNO: I agree with Dr. Kroll, and I
21 agree with Dr. Bush. I might suggest that on the more
22 obvious, the next five, that we have any database on,

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1 that you could refer to the College of American
2 Pathology, and the American Association of Clinical
3 Chemistry has a database that could provide us a good
4 starting point for establishing cutoffs, because they
5 have had an accreditation program for a while.

6 I don't know whether I totally agree with
7 all of them or not, but at least it is a point to
8 start at.

9 MR. LEWIS: Sherwood Lewis. I have
10 nothing.

11 DR. HENDERSON: I certainly think that
12 this panel should be expanded to those other than what
13 is included in SAMHSA.

14 DR. ROSENBLOOM: Yes. I mean, yes, I
15 agree with everybody.

16 DR. KROLL: Very good. Dr. Gutman, do you
17 have any more questions that need to be clarified on
18 this issue?

19 (No audible response.)

20 DR. KROLL: I would like to thank the
21 panel for going through this succinctly, and is there
22 any issue that any panel member would like to clarify

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1 in any of their comments? Now is a good time to do
2 it.

3 DR. WILKINS: Actually, I want to clarify
4 a comment that I made before the break, and that was
5 the issue of distinguishing between the labeling
6 guidelines on home-use kits, versus insurance and
7 sports testing. And the issue of confirmation
8 testing.

9 It was my intent to say that I thought it
10 should be clearly labeled whether the intent of the
11 kit was -- what the intended use was by the
12 manufacturer is what I meant there.

13 I did not mean to imply that confirmation
14 testing should not be done in any of those settings.
15 It was my position that I felt that confirmation
16 testing should occur in all of those settings.

17 However, I think that the kit insert or
18 package insert should clearly state what the intended
19 purpose of the kit is, or the setting in which it
20 should be applied, because I think there may be
21 interpretation issues associated with that that the
22 consumer might need to be aware of.

1 DR. KROLL: All right. Any other panel
2 members have comments? If not, at this time, since we
3 have some time left, if there is some people among the
4 public observers, if they would like to make a very
5 short, brief comment, limited to about maybe 3 or 4
6 minutes, they can make it at this time.

7 MR. AROMANDO: Bob Aromando. As I
8 mentioned earlier, I am an independent consultant. I
9 just wanted to address 1 or 2 points that were
10 mentioned this afternoon. Just as an example, if we
11 went back to question eight, where it is stated that
12 visually read devices frequently render positive
13 results well below claimed cutoff.

14 Well, this also occurs in instrument based
15 tests, and Donna Bush, of all people, would know that
16 this does occur, since these instruments rely daily on
17 calibration curves that tend to drift from one hour to
18 the next. So this is fact.

19 Secondly, if a visual test calls samples
20 positive below the cutoff, the confirmation test will
21 usually agree, and I use cocaine as an example, which
22 has a 300 nanogram cutoff value, and if some of these

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1 visual tests are picking up positives at 200 nanogram,
2 the cutoff value for confirmation tests is 150
3 nanogram. So it will pick it up, and there is no
4 question about it that it will confirm the result.

5 The other issue that I wanted to make was
6 that I don't think -- and unless I heard something
7 differently here, nobody is disagreeing that
8 confirmation tests should or should not occur. We all
9 agree that they are absolutely extremely important in
10 every single case.

11 But I also heard some comment about
12 confirming negative results, which is probably
13 physically impossible in this country considering that
14 90 percent or more of drug test results are negatives.
15 I don't think any lab in this country is equipped to
16 confirm every negative result that potentially could
17 be out there.

18 There also seems to be concerns
19 specifically about confirming screen results in the
20 workplace and it must be known that just about every
21 State in this country requires drug testing results to
22 be confirmed before any action takes place.

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1 So there are State laws already in place
2 to protect employees, and there are also union
3 contracts that require confirmation testing as well.
4 So there is no disagreement here.

5 The other thing that I would like to just
6 go back to, is that early on in the day there was some
7 statement about on-site testing being more expensive,
8 and I think it was Donna Bush who may have said that.

9 Well, perhaps that may be the case, but a
10 lab based test is extremely, and I go back to my
11 statement earlier where when labs are allowed to
12 dilute or water down reagents for the sake of economic
13 purposes, certainly they are going to be less
14 expensive.

15 But at the end of the day, if you look at
16 the total cost of ownership on on-site drug tests, it
17 is less expensive, because the results are immediately
18 available, especially in a workplace testing
19 environment, where a candidate can be hired
20 immediately upon a negative result, versus several
21 days for a negative result from a laboratory. Thank
22 you.

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1 DR. KANG: Thank you, Dr. Kroll and
2 panelists. I am Jemo Kang from Princeton BioMeditech
3 Corporation. We make about 42 products, FDA-cleared
4 products, all point-of-care direct assay.

5 And we are more acutely aware of the
6 problems with assays, and first I would like to make
7 some comments on confirmation. If we package products
8 and make consumers aware of the content, my question
9 is what are they buying.

10 Those test kits may cost under \$20, and if
11 you include confirmation requirements, it may go into
12 \$30 to \$50. What are the customers paying for? And
13 these issues about benefits and harm issues, can the
14 FDA make this available to customers.

15 The clear intent is to make this program
16 widely available at a reasonable cost. To me perhaps
17 the national goal of deterring drug use. If the test
18 unnecessarily, because of confirmation requirements,
19 cost twice or three times -- and if they have to pay
20 \$40 or \$50 for tests, many of the customers may have
21 to think about whether they want to buy test kits to
22 test their children, or they would like to buy a bag

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1 of groceries to prepare for supper.

2 It is a difficult issue and decision, and
3 I think the one object to make this test widely
4 available, readily available to customers, is we are
5 not meeting that goal somehow.

6 And also from the point of the
7 manufacturer, there is a tendency of misusing the
8 confirmation issue, and currently I am hearing from
9 many other people that if they put over-the-counter
10 drug tests requiring confirmation, they are expecting
11 perhaps below 50 percent of the tests will come back
12 for confirmation.

13 That means that another 50 percent may
14 never send for confirmation. Those people who do not
15 send in for confirmation, they are also paying for
16 this confirmation test.

17 In case the test results are negative,
18 they are also penalized to pay for this confirmation
19 test. So my proposal is whether it would be possible
20 to make this over-the-counter product available a
21 different way. One way is packaging it as a purely
22 drug test, and then make confirmation tests available

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1 on the shelf to make it optional.

2 If that doesn't meet FDA's requirements to
3 ensure safe and effectiveness of this test, perhaps
4 co-sharing, sharing the costs or sharing the bottom
5 with the manufacturer may be one option.

6 If a confirmation test requirement may
7 cost \$30, perhaps the manufacturers could share half-
8 and-half. Therefore, it may be possible to use the
9 test price lower to customers, and that might actually
10 help to make this test more widely available.

11 If the packaging says we are detecting the
12 presence of drug rather than -- what was the language
13 again -- well, rather than the impairment of the
14 individuals. That says two things. We are concerned
15 about concentration or presence of drugs in the
16 sample.

17 That to me is more of a legal issue, which
18 later part addresses medical use. That may bring
19 jurisdiction issues. If you are talking about simple
20 presence or non-presence of drug, which does not apply
21 any medical implications, why are you talking about
22 that.

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1 And also as a manufacturer, I know some
2 panel members raised the issue of whether we can make
3 approximations about 50 percent, and whether we can
4 tighten further. In principle, it is a very good idea
5 to make the test highly accurate.

6 But we have to think about what is
7 possible in the hands of a lay person. It is very,
8 very difficult to distinguish at 50 percent cutoff
9 level, a positive or negative issue in the eyes of
10 many customers. It is not easy. I think tightening
11 further is not really adding more benefit to the
12 customers. Thank you very much.

13 DR. KROLL: Thank you. Dr. Lewis, did you
14 want to make a comment?

15 DR. LEWIS: Sherwood Lewis.

16 DR. KANG: If I could add one more thing.
17 The last question was about whether we should follow
18 SAMHSA guidelines cutoff rather than if we want to
19 include only SAMHSA or NIDA-5 drugs. I noticed that
20 most of the panelists was talking about adding more
21 drugs rather than talking about whether we should
22 stick to the cutoff level of SAMHSA.

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1 DR. KROLL: Dr. Lewis.

2 DR. LEWIS: Sherwood Lewis. I just wanted
3 to respond to the statement that was made regarding
4 the testing of all negative results. I did not
5 suggest that all negative results be confirmed. I was
6 saying what would happen should an individual want as
7 part of the package as purchased to have a negative
8 result sent out for confirmation. I certainly
9 appreciate that you can't confirm all negatives.

10 MR. AROMANDO: I'm sorry, but maybe it was
11 not you, Dr. Lewis, but there was -- and I am sure
12 that we have transcripts here, but it was almost
13 verbatim that it was suggested that all negatives be
14 confirmed.

15 And again that was my response, was that
16 that is physically and logistically impossible to
17 confirm all negative results.

18 DR. LEWIS: I thought you were referring
19 to my comment.

20 MR. AROMANDO: What was the intent of the
21 document.

22 DR. GUTMAN: The intent of the document

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1 was to look only at positives.

2 MR. AROMANDO: We are in agreement with
3 that. And before I just give this to Dave, there was
4 just one other last comment, and there was another
5 comment made earlier that wet chemistry DATs are more
6 accurate than on-site drug review tests.

7 So, first, I'm curious to know how many
8 studies are we drawing our conclusion from, and in
9 what peer review publications have these studies been
10 reviewed.

11 And secondly there are currently several
12 dozen studies, including one that was commissioned by
13 SAMHSA that have beyond a doubt established a level of
14 performance of these on-site drug tests comparable to
15 lab-based wet chemistry drug tests.

16 In another study conducted by the
17 Administrator of the U.S. Court, about 3 or 4 years
18 ago, in fact the lab test for the amphetamines used in
19 the study showed a 27 percent false positive rate,
20 versus a zero percent false positive rate for some of
21 the on-site amphetamine tests.

22 DR. KROLL: Thank you. Can we keep our

1 comments down to about 3 minutes.

2 MR. EVANS: I promise not to talk about
3 legal issues. I flunked chemistry in high school, and
4 that is the reason that I did not become a doctor. I
5 come from a long line of doctors, but I learned enough
6 to know about the scientific method.

7 And you are about to make a decision that
8 is going to affect thousands of businesses and a lot
9 of people, and I am asking you to slow the process
10 down a little bit, and just ask if you have gotten the
11 evidence that you all need.

12 I would urge you to have more hearings,
13 and get more evidence, talk to the users of the on-
14 site tests, especially DOT people that have been using
15 them for years. I urge you to talk to the people from
16 the United States Postal Service that are doing
17 hundreds-of-thousands of these tests.

18 That may alter some of your decisions.
19 Again, look at the evidence and see what is really
20 going on. Talk to people from all different
21 categories -- industry, workplace, insurance, sports,
22 and schools.

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1 We went through this process with SAMHSA
2 over the last 2 or 3 years, and they kept an open
3 mind. Many of the members of the drug testing advisor
4 board had a mindset against on-site testing when we
5 started.

6 I think we worked out something that is
7 acceptable to us and acceptable to them, and that
8 guarantees a good reliable test that will be used in
9 a good reliable way. I would ask you to look at their
10 studies and hear some of the same evidence that they
11 heard before you make up your mind.

12 I am a little concerned that you are
13 rushing to judgment. This guidance could come out
14 within about 90 days and you may be making a mistake.
15 I am a former bureaucrat, and I once exceeded my
16 authority, and I got slapped by a court, and I never
17 forgot it, and they were absolutely right. I had done
18 the wrong thing.

19 I had not looked at the evidence when I
20 made a decision as a bureaucrat. It is embarrassing
21 and it made the front page of the legal newspaper in
22 New Jersey with my photograph on it. So I am acutely

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1 sensitive to this, and I learned a great lesson from
2 it.

3 And I would urge you to look at the
4 consumer protections that are already built in. I
5 don't think you have gotten enough evidence about
6 that. I don't think you have gotten enough evidence
7 about the intent of Congress.

8 Congress recently passed a law probating
9 \$10 million for drug free workplace programs, and a
10 Congressional committee specifically said they wanted
11 on-site testing included in that.

12 So I would ask you to keep an open mind,
13 and walk through the process with us like SAMHSA did,
14 and I really think they came up with something that is
15 really going to protect everybody. Thanks.

16 MS. HOGAN: I promise to be very brief.

17 DR. KROLL: Could you state your name,
18 please.

19 MS. HOGAN: Absolutely. My name is
20 Lorraine Hogan, and I am a California licensed
21 clinical toxicologist scientist. I have a seven year
22 history in working in the SAMHSA laboratory. I am not

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1 a product manager.

2 Historically, I worked for Phamatech,
3 which was the first over-the-counter cleared drug
4 test. I have moved on to another in-vitro diagnostic
5 manufacturer, but I probably have more direct
6 experience talking to the end-user from these products
7 than anybody, because I wrote the training manual for
8 the support representatives that handle the toll-free
9 number for Pharmatech.

10 I can tell you that my recommendation
11 would be that we look at the package insert and maybe
12 back up a little bit and explain why confirmation
13 tests are needed. I think that the principle of
14 immunoassay is something that escapes most consumers
15 and lay people.

16 If you couch it in the manner that they
17 understand why chemically similar compounds will react
18 and that it is not necessarily -- it is a limitation
19 of the assay, but it does not make the assay a bad
20 assay.

21 I think that right now that things are
22 couched in a manner that people think that the test is

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1 not good. I know originally the term inconclusive was
2 used for a presumptive positive result.

3 Also, I think that it is important that
4 toll free numbers in any over-the-counter product,
5 particularly medical devices, are built and that they
6 are administrated well in consumer feedback,
7 particularly on a high stress level product like this,
8 is extremely -- there are a lot of people that call
9 and ask questions that are clearly stated in the
10 package inserts, but that they just did not seem to
11 understand.

12 And, Dr. Lewis, I can assure you that with
13 Phamatech's product, the fact that the confirmation
14 cost is built into it, there are numerous people that
15 send their negative results in because they want that
16 extra feeling of comfort.

17 So people do send negative results in. We
18 have to explain to them why the intensity of the line
19 was light, for example, and this is built into the
20 assay.

21 We have to explain why light intensity was
22 light, and sometimes it gets into a technical

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1 dissertation about cross-reactivities. But I think
2 that confirmation is relevant.

3 I think it is relevant to have a mechanism
4 built in for confirmation testing to be done, but not
5 necessarily to include the cost of it. I don't think
6 people truly understand the two step process of a drug
7 test when you get to a consumer individual.

8 DR. KROLL: Thank you very much. Dr.
9 Gutman, are there any other issues that we should
10 address? Well, I think maybe you could submit those
11 in writing.

12 DR. KANG: I forgot to mention one comment
13 about Dr. Gutman discussed; including more information
14 about the product. My suggestion is pregnancy and
15 ovulation tests on the market as an over-the-counter
16 product, and our company has that product on the
17 market. Clinical guidelines do not require
18 performance data in OTC product packaging, sir, and
19 that has worked quite well.

20 And from my experience, even if we give
21 more information, there will always be a lot of
22 questions, and we have an 800 number for customers.

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1 We receive a lot of telephone calls about the
2 implications, and it seems to be working fine.

3 But adding more information, more
4 confirmation, more customer data in the packaging
5 insert, is not necessarily helpful, and would probably
6 have to be made very, very small because of the
7 limited space in the packaging.

8 DR. KROLL: All right. Thank you for your
9 comments. Dr. Gutman, do you have any questions or
10 comments that you would like to make?

11 DR. GUTMAN: No, I would like to thank you
12 all for bearing with us, and giving us this input.

13 DR. KROLL: All right. Are there any
14 other comments from the panel members?

15 DR. KURT: Tom Kurt. I would like to
16 comment that outside of the realm of the DOT, some
17 people used the word confirmation in a more broader
18 context, and tried to confirm by FPIA and other
19 methods, which are really not state-of-the-art
20 confirmations.

21 So I would like to point out how
22 confirmation is really defined in your documents and

1 labeling.

2 DR. KROLL: Well, thank you very much. I
3 would like to thank all the panel members for all
4 their efforts today and thoughtful comments. And I
5 would also like to thank all the staff members and
6 especially Veronica Calvin, our executive secretary,
7 who has been writing here like crazy, and all the
8 other people involved with the FDA staff, Dr. Gutman,
9 and everyone else. Thank you.

10 DR. ROSENBLOOM: I would like to request
11 a change in the seating arrangement tomorrow.

12 MS. CALVIN: I have just a couple of
13 comments to make before we leave. I just want to echo
14 my thanks, and as Dr. Kroll indicated, to all the
15 panel, FDA staff in particular, and the public
16 speakers.

17 And if anyone was shy or has additional
18 comments, as I think Mr. Evans alluded to, the comment
19 period is open for 90 days after the notice of
20 announcement in the Federal Register, which was around
21 the beginning of November. So I guess that brings you
22 to probably late January or early February.

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1 Also, if you found today's discussion to
2 be very interesting, we invite you back tomorrow. The
3 panel will be discussing a device application that
4 detects drugs-of-abuse in hair. Thank you.

5 (Whereupon, the panel adjourned at 4:40
6 p.m.)
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CERTIFICATE

This is to certify that the foregoing transcript
in the matter of: MEETING

Before: CLINICAL CHEMISTRY AND CLINICAL
TOXICOLOGY DEVICES PANEL

Date: NOVEMBER 13, 2000

Place: GAITHERSBURG, MARYLAND

represents the full and complete proceedings of the
aforementioned matter, as reported and reduced to
typewriting.

Rebecca Davis